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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**Applicants** : Wagner

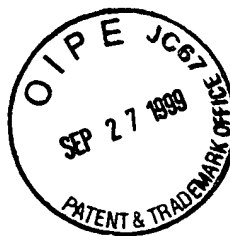
**Serial No** : 09/087,871

**Filed** : June 2, 1998

**Group Art Unit** : 1641

**Examiner** : GABEL, G.

**For** : ***AUTOMATED DIAGNOSTIC SYSTEM IMPLEMENTING  
IMMUNOASSAYS AND CLINICAL CHEMISTRY ASSAYS  
ACCORDING TO A REFLEX ALGORITHM***



**RESPONSE TO REQUIREMENT FOR RESTRICTION  
UNDER 35 U.S.C. §121**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Applicant presents the following remarks in response to the Official Action dated June 23, 1999. The present response is accompanied by a Petition for Extension of Time with fee payment authorization.

In the Office Action, restriction in this case under 35 U.S.C., §121, is required to one of the following inventions:

I. Claims 1-8, drawn to a diagnostic system comprising different analyzers, classified in class 73, subclass 863.03, for example;

II. Claims 9-12, drawn to biological marker measurements, classified in class 128, subclass 632, for example;

III. Claims 13-15, drawn to a computer program and computer readable medium, classified in class 266, subclass 80, for example;

IV. Claims 16-21, drawn to automated diagnostic system, classified in class 395, subclass 183.15, for example.

According to M.P.E.P. §803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (1) The inventions must be independent or distinct as claimed; and
- (2) There must be serious burden on the examiner if restriction is not required.

M.P.E.P §802.01 gives the definition of the term "distinct" as follows:

The term "distinct" means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process, and product made, etc. but are capable of separate manufacture, use, or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER (though they may each be unpatentable because of the prior art).

In the Office Action, Invention II is considered a process that is distinct from apparatuses for its use of Inventions I and IV. As noted in the Office Action, based on the guidelines set forth under MPEP §806.05(e), such related inventions are distinct if it can be shown that either (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. The Office Action asserts that Invention II is distinct (i) from Invention I because "Group II can be performed manually (by hand) utilizing a kit with corresponding reagents necessary", and (ii) from Invention IV because "Group II can be performed using basic manually programmed

analyzers”.

Additionally, the Office Action states that Invention I and III as well as Inventions III and IV are related as subcombinations disclosed as usable together in a single combination. As noted in the Office Action, according to MPEP §§ 806.05(d), subcombinations are distinct from each other if they are shown to be separately usable. The Office Action asserts (i) Inventions I and III are distinct because “invention I has separate utility such as the diagnostic system can be manually programmed to perform the sequence of biochemical analyses”, and (ii) Inventions II and IV are distinct because “invention III has separate utility such as incorporation into other analyzers to program reflexive testing for hepatic function testing or thyroid function testing.”

Consequently, the Office Action states that because the inventions are distinct according to the above reasoning and, have acquired a separate status in the art as shown by the identified different classifications, restriction for examination purposes as indicated is proper.

Applicant respectfully traverses the requirement for restriction.

First, Applicant notes that the Office Action sets forth Invention II as directed to a process and Invention IV as directed to an apparatus (*see, e.g.*, ¶¶1-3 and 5); however, the claims grouped into Inventions II are apparatus claims, and those grouped into Invention IV are process claims. Accordingly, Applicant respectfully submits that the Office Action’s reasoning to assert distinct inventions is inapposite, and thus the requirement for restriction is improper and should be withdrawn. Applicant requests that if a restriction requirement is maintained or further asserted, that the reasoning be set forth with respect to the statutory subject matter of the claims.

Second, to the extent that a proper restriction requirement has been or will be

made, however, Applicant respectfully traverses such requirement on the grounds that the inventions are obvious over each other within the meaning of 35 USC § 103. Accordingly, as indicated in MPEP §803, restriction should not be required. *In re Lee*, 199 USPQ 108 (Comm'r Pat. 1978).

Additionally, Applicant respectfully traverses the requirement on the grounds that it would not be unduly burdensome for the Examiner to search the fields of all Inventions. More specifically, based on the similarity in claimed subject matter among Inventions I-IV as grouped in the Office Action, in searching the claims of a given Invention, the Examiner should also search for the art pertaining to the other Inventions as grouped in order to be sure that all pertinent art is considered for a proper examination on the merits. Applicant notes that each of the groups of claims as set forth in the Official Action relates to commanding or controlling automatic execution of immunoassay and clinical chemistry assay measurements according to a representation of a "decision tree" or a "reflex algorithm. Accordingly, Applicant submits that in order to provide a complete and exhaustive search of any of the inventions as grouped in the Office Action, the search should include the search directed to each of the other inventions as grouped in the Office Action. Moreover, it is also believed that it would not be unduly burdensome for the Examiner to search the classifications for all inventions.

In view of the foregoing, Applicant respectfully requests that the requirement for restriction be withdrawn.

Notwithstanding the foregoing grounds for traversal, Applicant provisionally elects to prosecute claims 1-8, which correspond to Invention I from among Inventions I-IV into which the Office Action has classified the present invention.

The Examiner's consideration of this matter is gratefully acknowledged.

Respectfully submitted,

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Date: September 23, 1999

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